

**LISTING OF THE CLAIMS**

1. (Previously presented) A pharmaceutical composition for enteric delivery of one or more pharmaceutically active amphetamine salts comprising: (a) one or more pharmaceutically active amphetamine salts covered with an immediate release coating; and (b) one or more pharmaceutically active amphetamine salts that are covered with an enteric release coating that provides for pulsed enteric release wherein the enteric release coating has a thickness of at least 25 $\mu$ ; wherein the pharmaceutically active amphetamine base salts comprise dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate and amphetamine sulfate.
2. (Original) The pharmaceutical composition of claim 1 wherein the one or more pharmaceutically active amphetamine salts are coated onto a core.
3. (Original) The pharmaceutical composition of claim 1 wherein the one or more pharmaceutically active amphetamine salts are incorporated into a core.
4. (Original) The pharmaceutical composition of claim 1, wherein the immediate release and enteric release portions of the composition are present on a single core.
5. (Original) The pharmaceutical composition of claim 1, wherein the immediate release and enteric release components are present on different cores.

6. (Previously presented) A pharmaceutical composition for enteric delivery of one or more pharmaceutically active amphetamine salts comprising: (a) one or more pharmaceutically active amphetamine salts covered with an immediate release coating; (b) one or more pharmaceutically active amphetamine salts that are covered with an enteric release coating that provides for pulsed enteric release; and (c) a protective layer between the at least one pharmaceutically active amphetamine salt and the enteric release coating;
- wherein the pharmaceutically active amphetamine base salts comprise dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate and amphetamine sulfate.
7. (Original) The pharmaceutical composition of claim 6 wherein the one or more pharmaceutically active amphetamine salts are coated onto a core.
8. (Original) The pharmaceutical composition of claim 6 wherein the one or more pharmaceutically active amphetamine salts are incorporated into a core.
9. (Original) The pharmaceutical composition of claim 6 wherein the enteric release coating has a minimum thickness of 25 $\mu$ .
10. (Previously presented) A pharmaceutical composition for delivering one or more pharmaceutically active amphetamine salts comprising: (a) one or more pharmaceutically active amphetamine salts covered with an immediate release coating; (b) one or more pharmaceutically

active amphetamine salts that are covered with an enteric release coating that provides for pulsed enteric release; and (c) a protective layer over the enteric release coating; wherein the pharmaceutically active amphetamine base salts comprise dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate and amphetamine sulfate.

11. (Original) The pharmaceutical composition of claim 10 wherein the one or more pharmaceutically active amphetamine salts are coated onto a core.

12. (Original) The pharmaceutical composition of claim 10 wherein the one or more pharmaceutically active amphetamine salts are incorporated into a core.

13. (Original) The pharmaceutical composition of claim 10, wherein the immediate release and enteric release portions of the composition are present on a single core.

14. (Original) The pharmaceutical composition of claim 10, wherein the immediate release and enteric release components are present on different cores.

15. (Previously presented) A pharmaceutical composition for delivery of at least one amphetamine salt, comprising: (a) at least one pharmaceutically active amphetamine salt covered with an immediate release coating; and (b) at least one pharmaceutically active amphetamine salt covered with an enteric release coating, the component (a) providing for an immediate release of amphetamine salt to provide a first blood level of amphetamine salt and component (b) providing a

delayed pulsed-release of amphetamine salt that increases the blood level of amphetamine salt to a second level that is greater than the first level provided by component (a);  
wherein the pharmaceutically active amphetamine base salts comprise dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate and amphetamine sulfate.

16. (Original) The pharmaceutical composition of claim 15 wherein the enteric release coating has a minimum thickness of 25 microns.

17. (Original) The pharmaceutical composition of claim 15 wherein the delayed pulsed-release is from 4 to 6 hours after administration of the pharmaceutical composition.

18. (Canceled)

19. (Previously presented) A pharmaceutical composition for delivery of one or more pharmaceutically active amphetamine salts comprising:

an immediate release component comprising at least one amphetamine base or salt associated with an immediate release coating;

a delayed release component comprising at least one amphetamine base or salt associated with a delayed release coating; and

a pharmaceutically acceptable carrier;

wherein the composition is sufficient to maintain an effective amphetamine level in a patient over the course of at least about 8 hours; and

wherein the one or more pharmaceutically active amphetamine salts comprise dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate and amphetamine sulfate.

20. (Previously presented) The composition of claim 19, wherein the plasma concentration of amphetamine over time corresponds to a plot having an area under the curve (AUC) of about 467 to about 714 ng hr/ml for a total amphetamine dose of about 20 mg.

21. (Previously presented) The composition of claim 19, wherein the one or more pharmaceutically active amphetamine salts and release components are provided on a substrate core.

22. (Previously presented) The composition of claim 20, wherein amphetamine and immediate release components are provided on the same core as amphetamine and delayed release components.

23. (Previously presented) The composition of claim 21, wherein the amphetamine and release components are provided in layers.

24. (Previously presented) The composition of claim 23, wherein each layer individually comprises at least one pharmaceutically active amphetamine or release component.



31. (Previously presented) The composition of claim 26, 27 or 28 wherein the AUC is about 714 ng hr/ml.
32. (Previously presented) The composition of claim 26, 27 or 28, wherein  $C_{\max}$  is about 40 ng/ml.
33. (Previously presented) The composition of claim 19, wherein the pharmaceutically active amphetamine salts are provided in about the same amounts.
34. (Previously presented) The composition of any of claims 19-32, wherein the delayed rapid release component comprises a polymer coating having a thickness of greater than  $20\mu$ .
35. (Previously presented) The composition of claim 33 wherein the thickness is at least  $25\mu$ .
36. (Previously presented) The composition of claim 19 formulated for a total amphetamine dose of 20 mg.
37. (Previously presented) The composition of claim 19 formulated for a total amphetamine dose having an AUC proportional to the AUC of a composition formulated for a 20 mg total amphetamine dose.

38. (Previously presented) The composition of claim 20 formulated for a total dose of 20 mg.

39. (Previously presented) The composition of claim 20 formulated for a total amphetamine dose other than about 20 mg and having a  $C_{\max}$  proportional to the  $C_{\max}$  for a 20 mg total amphetamine dose.

40. (Previously presented) The composition of claim 19, wherein the delayed release component is pH independent.

41. (Previously presented) The composition of claim 19, which further comprises a protective coating layer.

42. (Previously presented) A pharmaceutical composition for delivery of a mixture of amphetamine base salts effective to treat ADHD in a human patient comprising:

(a) amphetamine base salts covered with an immediate release coating that provides immediate release of the amphetamine base salts upon oral administration to the patient;

(b) amphetamine base salts covered with an enteric release coating that provides delayed release upon oral administration to the patient; and  
a pharmaceutically acceptable carrier;

wherein the amphetamine base salts comprise dextroamphetamine sulfate,  
dextroamphetamine saccharate, amphetamine aspartate monohydrate and amphetamine sulfate;



the pharmaceutical composition is sufficient to maintain an effective level of amphetamine base salts in the patient over the course of at least 8 hours; and

the plasma concentration versus time curve (ng/ml versus hours) in a human patient, for a selected total dose of amphetamine, has an area under the curve (AUC) proportional to about 467 to about 714 ng hr/ml. for a total amphetamine dose of 20 mg.

43. (Previously presented) The composition of claim 41, wherein the peak plasma concentration of amphetamine provided by release of the amphetamine base salts covered with an enteric release coating exceeds the peak plasma concentration provided by the release of the amphetamine base salts covered with an immediate release coating.

44. (Previously presented) The composition of claim 41, wherein the amphetamine base salts covered with an immediate release coating and the amphetamine base salts covered with an enteric release coating are present on a same core.

45. (Previously presented) The composition of claim 41, wherein the amphetamine base salts covered with an immediate release coating and the amphetamine base salts covered with an enteric release coating are present on different cores.

46. (Previously presented) The composition of claim 41, wherein the plasma concentration curve has a maximum concentration ( $C_{\max}$ ) of about 22.5 to about 40 ng/ml for about a total dose of 20 mg.

47. (Previously presented) The composition of claim 45, wherein the time after the oral administration to reach the  $C_{\max}$  value is about 7 to about 10 hours.

48. (Previously presented) The composition of claim 41, wherein the time after the oral administration to reach maximum concentration of the plasma concentration curve is about 7 to about 10 hours.

49. (Previously presented) The composition of claim 46, wherein the AUC is about 714 ng hr/ml, the time after the oral administration to reach the  $C_{\max}$  value is about 7 hours and  $C_{\max}$  is about 40 ng/ml.

50. (Previously presented) The composition of claim 45 wherein  $C_{\max}$  is about 40 ng/ml.

51. (Previously presented) The composition of claim 45 or 46 wherein the time is about 7 hours.

52. (Previously presented) The composition of claim 41 wherein each of the amphetamine salts is provided in about equal amounts.

53. (Previously presented) A pharmaceutical composition for delivery of a mixture of amphetamine salts effective to treat ADHD in a human patient comprising:

- (a) amphetamine salts covered with an immediate release coating that provides immediate release of the amphetamine base salts upon oral administration to the patient;
  - (b) amphetamine base salts covered with an enteric release coating that provides delayed release upon oral administration to the patient; and
  - (c) a pharmaceutically acceptable carrier;
- wherein the amphetamine base salts comprise dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate and amphetamine sulfate;
- the enteric release coating has a thickness greater than  $20\mu$ , comprises a dried aqueous dispersion of an anionic copolymer based on methacrylic acid and acrylic acid ethyl ester, and is soluble at a pH of about 5.5 upwards; and
- the pharmaceutical composition is sufficient to maintain an effective level of amphetamine in the patient over the course of at least 8 hours.

54. (Previously presented) The composition of claim 52, wherein the amphetamine salts covered with an immediate release coating and the amphetamine salts covered with an enteric release coating are present on a same core.

55. (Previously presented) The composition of claim 52, wherein the amphetamine salts covered with an immediate release coating and the amphetamine base salts covered with an enteric release coating are present on different cores.

56. (Previously presented) The composition of claim 52, wherein the delayed release is pH independent.

57. (Previously presented) The composition of claim 52, which further comprises a protective coating layer.